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EXAMINER

ODLAND, KATHRYN P

ART UNIT PAPER NUMBER

3743

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Please find below and/or attached an Office communication concerning this application or proceeding.



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GROUP 3700

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/751,271
Filing Date: December 28, 2000
Appellant(s): ALFERNESS ET AL.

James Shay
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 23, 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.
For clarification, claim 28 stands rejected as being unpatentable under 35 U.S.C. 103 (a) in view of Houser. Although, the numeral was inadvertently listed under the 35 U.S.C. 102(e) rejection, the subject matter and claim number is clearly discussed in the 35 U.S.C. 103 (a) in view of Houser, on page 13 of the final office action.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 25-30 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

US 2002/0035361 Houser 3-2002

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 25-27 stand rejected under 35 U.S.C. 102(e). This rejection is set forth in a prior Office Action, mailed on March 11, 2004.

Claims 28-30 rejected under 35 U.S.C. 103(a). This rejection is set forth in a prior Office Action, mailed on March 11, 2004.

(11) Response to Argument

In appellant's discussion of the Houser reference, appellant states, "While Houser shows many different clip embodiments, Houser discloses only one that may be delivered to the mitral valve annulus via the coronary sinus. However, the examiner respectfully disagrees and contends that the appellant has an extraordinarily narrow and improper interpretation of the Houser reference. Appellant is directed to Figures 27A and 27B of the Houser reference. These embodiments are clearly not unlike appellants. Appellant is also again directed to section [0128], which recites in reference to the clips, such as that of figures 27A and 27B, "The clip may be delivered and placed over or around the valve using a variety of different methods...." Houser in sections [0134]-[0140] discusses the possibility of inserting the catheter into the coronary vasculature, particularly the coronary sinus to deliver a clip. The example mentions clip

498a, which in a reasonably broad recitation is a generally C-shaped clip. Nonetheless, given the recitation that the clip may be placed over or around the valve using a variety of different methods, it is within a reasonably broad interpretation that any of the clips disclosed such as that shown in figures 27A and 27B can be delivered via the coronary vasculature as discussed in sections [0134]-[0140].

Appellant also argues, "As shown in Fig. 42, clips 498 are substantially straight. However, the examiner respectfully disagrees. The clips will have to be C-shaped for proper clamping, as shown in figures such as 31B. Nonetheless, the embodiment of figures 27A and 27B are not unlike appellants. Regarding the argument, "...Houser never describes the relative radii of the clips with respect to the valve annulus." Appellant is directed to figure 28, which pictorially depicts the clip relative to the annulus. Moreover, the scope of this limitation is dependent upon the application. The size and shape of the valve annulus will depend upon the size of the patient's heart. A child will most likely have a different sized annulus than an adult. Additionally, the valve annulus could differ quite substantially between human and other animals.

Appellant recites, "Houser does not describe any releasable coupling or uncoupling between the delivery mechanism and the clip, nor does Houser describe any relative movement between the catheter and the device during delivery or deployment." It appears appellant is again interpreting the claims overly narrow. Couple is defined as: to link together; connect according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. In a reasonably broad interpretation, the introducer assembly of Houser most certainly has a

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connection with the clip in order for it to be deployed. A plunger/introducer assembly as discussed by Houser can be considered a releasable coupling, for when the plunger forced the clip out of the housing they are released from contact. When they reside in the introducer at some point they are contacting each other in a connecting manner.

The examiner is required to interpret the claims reasonably broad in light of the specification and it appears appellant is taking a narrow interpretation of the claims and arguing limitations that are not claimed.

Group I

Regarding claim 25, appellant argues, "Houser, however, fails to disclose a device with the recited unstressed effective radius and does not show the advancement of any device to partially encircle the mitral valve." However, as discussed above, appellant is directed to figure 28. This figure clearly shows partially encircling of the mitral valve and the size and shape of the valve annulus will depend upon the size of the patient's heart. A child will most likely have a different sized annulus than an adult. Additionally, the valve annulus could differ quite substantially between human and other animals.

Group II

Regarding claims 26, Houser discloses an advancing step that includes releasably coupling the constrictive device to an elongated flexible introducer and moving the constrictive device into the coronary sinus with the introducer. Houser

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discloses introducers such as element 436. Couple is defined as: to link together; connect according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. In a reasonably broad interpretation, the introducer assembly of Houser most certainly has a connection with the clip in order for it to be deployed. A plunger/introducer assembly as discussed by Houser can be considered a releasable coupling, for when the plunger forced the clip out of the housing they are released from contact. When they reside in the introducer at some point they are contacting each other in a connecting manner.

Regarding claim 28, sheaths are extraordinarily well known in the art and introducers are commonly within sheaths. This feature is so well known in the catheter art that it would be obvious to one with ordinary skill in the art to include a sheath as a guide for the introducer for the purpose of more controlled delivery.

Group III

Regarding claim 27, appellant argues, "As stated above, however, Houser's plunger and stylet are never coupled to Houser's device." However, the examiner respectfully disagrees. Couple is defined as: to link together; connect according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. In a reasonably broad interpretation, the introducer assembly of Houser most certainly has a connection with the clip in order for it to be deployed. A plunger/introducer assembly as discussed by Houser can be considered a releasable coupling, for when the plunger forced the clip out of the housing they are

released from contact. When they reside in the introducer at some point they are contacting each other in a connecting manner. Appellant has not given a special definition to the term "couple" and appears to be arguing a narrow interpretation of the term.

Regarding claim 29, the introducer is most certainly released from the constrictive device during deployment and the introducer will be removed from the patient. Claim 29 depends from claim 28, and as discussed above, sheaths are extraordinarily well known in the art and introducers are commonly within sheaths. This feature is so well known in the catheter art that it would be obvious to one with ordinary skill in the art to include a sheath as a guide for the introducer for the purpose of more controlled delivery.

Group IV

Regarding claim 30, as discussed above, sheaths are extraordinarily well known in the art and introducers are commonly within sheaths. This feature is so well known in the catheter art that it would be obvious to one with ordinary skill in the art to include a sheath as a guide for the introducer for the purpose of more controlled delivery. In light of the modification, the method steps would necessarily and inherently correspond to this modification.

For the above reasons, it is believed that the rejections should be sustained.

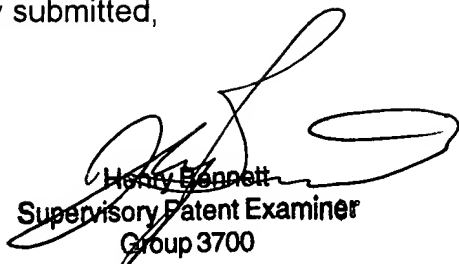
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Respectfully submitted,

KO 
November 28, 2004

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